

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

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Date of mailing
(day/month/year)

23 OCT 2008

Applicant's or agent's file reference
782-P08-046

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/US 08/57948

International filing date (day/month/year)

21 March 2008 (21.03.2008)

Priority date (day/month/year)

22 March 2007 (22.03.2007)

International Patent Classification (IPC) or both national classification and IPC

IPC(8) - A61F 2/02 (2008.04)

USPC - 623/11.11

Applicant MARCTEC, LLC

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☒ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450, Alexandria, Virginia 22313-1450
Facsimile No. 571-273-3201

Date of completion of this opinion

6 October 2008 (06.10.2008)

Authorized officer:

Lee W. Young

PCT Helpdesk: 571-272-4300
PCT OSP: 571-272-7774

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Box No. I Basis of this opinion

1. With regard to the **language**, this opinion has been established on the basis of:
- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into _____ which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43*bis*.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of:
- a. type of material
- ☐ a sequence listing
- ☐ table(s) related to the sequence listing
- b. format of material
- ☐ on paper
- ☐ in electronic form
- c. time of filing/furnishing
- ☐ contained in the international application as filed
- ☐ filed together with the international application in electronic form
- ☐ furnished subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

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Box No. IV Lack of unity of invention

1. ☒ In response to the invitation (Form PCT/ISA/206) to pay additional fees the applicant has, within the applicable time limit:
- ☒ paid additional fees
- ☐ paid additional fees under protest and, where applicable, the protest fee
- ☐ paid additional fees under protest but the applicable protest fee was not paid
- ☐ not paid additional fees
2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose not to invite the applicant to pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rule 13.1, 13.2 and 13.3 is

☐ complied with

☒ not complied with for the following reasons:

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In order for all inventions to be examined, the appropriate additional examination fees must be paid.

Group I: Claims 1-10 and 20, directed to a weldable plate assembly for attachment to a tissue or implant material comprising an anchor, wherein the anchor or plate may be welded.

Group II: claims 11-19, directed to a method of stabilizing a bone comprising placing a rod into a cavity of the bone, inserting a fastener through the bone to exert a biasing force on the rod, and welding the fastener to the rod.

The inventions listed as Groups I - II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of the Group I claims is providing a weldable plate and anchor assembly for attachment to tissue - not required by the claims of Group II. The special technical feature of the Group II claims is a means of securing a bone via welding a medullary-placed rod in a biased manner to a securing anchor - not required by the claims of Group I. Neither of these special technical features is common to the other group, nor do they correspond to a special technical feature in the other group.

The only common technical element shared by the above groups is that they are related to welding bone or tissue implants or portions thereof to secure them to each other. While it may be possible to use the invention of Group I in conjunction with the invention of Group II, welded implant materials apparatus useful for forming them do not represent an improvement over the prior art of US 2006/0122600 A1 to Cole (8 June 2006) (see para [0082]).

Therefore, the inventions of Group I and Group II lack unity of invention under PCT Rule 13 because they do not share a same or corresponding special technical feature.

4. Consequently, this opinion has been established in respect of the following parts of the international application:

☒ all parts

☐ the parts relating to claims Nos. _____

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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	2-10, 12, 16	YES
	Claims	1, 11, 13, 14, 15, 17-19, 20	NO
Inventive step (IS)	Claims	none	YES
	Claims	1-20	NO
Industrial applicability (IA)	Claims	1-20	YES
	Claims	none	NO

2. Citations and explanations:

Claim 1 lacks novelty under PCT Article 33(2) as being anticipated by US 2004/0030341 A1 to Aeschlimann et al. (hereinafter Aeschlimann).

As per claim 1, Aeschlimann discloses a weldable plate assembly for attachment to a first tissue or implant material (para [0057]) comprising:

a plate having a first receptacle formed on a first side of the plate (para [0057]);
an anchor having a longitudinal axis, a distal end and a proximal end, wherein the distal end is configured for insertion into the first tissue or implant material and the proximal end is configured for insertion into the receptacle formed on the plate (para [0063]; fig. 2);
wherein at least one of the anchor or plate can be welded when exposed to an energy source (para [0063]).

Claims 11, 13, 14, 15, and 17-19 lack novelty under PCT Article 33(2) as being anticipated by US 2006/0122600 A1 to Cole (hereinafter Cole).

As per claim 11, Cole discloses method of stabilizing a bone comprising the steps of:
placing a rod having a longitudinal axis into a cavity of the bone (para [0086-0087]);
inserting a fastener through the bone toward the rod at an angle that does not intersect the longitudinal axis of the rod (para [0082, 0090-0091]);
causing the fastener to exert a biasing force against a portion of the rod (para [0090]); and
welding the fastener to the rod (para [0082]). As per claim 13, Cole discloses the method of claim 11, and Cole further discloses wherein the biasing force exerted on the rod by the fastener urges the rod toward a wall of the bone cavity (para [0017, 0103, 0109]).

As per claim 13, Cole discloses the method of claim 11, and Cole further discloses wherein the biasing force exerted on the rod by the fastener urges the rod toward a wall of the bone cavity (para [0017, 0103, 0109]).

As per claim 14, Cole discloses the method of claim 11, and Cole further discloses wherein the fastener comprises a post that extends at least partially into the bone and contacts the rod, and wherein the post comprises an outwardly extending projection along at least a portion of the length of the post (para [0082-0083]).

As per claim 15, Cole discloses the method of claim 11, and Cole further discloses wherein the fastener comprises a plurality of posts extending at least partially into the bone and contacting the rod (para [0014-0015]; fig. 1).

As per claim 17, Cole discloses a method of stabilizing a bone comprising the steps of:
placing a rod having a longitudinal axis into a cavity of the bone (para [0086-0087]);
inserting a fastener through the bone toward the rod at an angle that does not intersect the longitudinal axis of the rod (para [0082, 0090-0091]);
causing the fastener to exert a biasing force against a portion of the rod (para [0090]); and
welding the fastener to the bone (para [0082]).

As per claim 18, Cole discloses the method of claim 17, and Cole further discloses wherein the biasing force exerted on the rod by the fastener urges the rod toward a wall of the bone cavity (para [0017, 0103, 0109]).

As per claim 19, Cole discloses the method of claim 17, and Cole further discloses wherein the fastener comprises a post that extends at least partially into the bone and contacts the rod, and wherein the post comprises an outwardly extending projection along at least a portion of the length of the post (para [0082-0083]).

-Continued in Supplemental Box-

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:

-*-Citations and Explanations - Box V.2-*-

Claim 20 lacks novelty under PCT Article 33(2) as being anticipated by US 6,605,090 B1 to Trieu et al. (hereinafter Trieu).

As per claim 20, Trieu discloses a plate assembly for fixation to a first tissue comprising:

a plate having at least one through hole for receiving a fastener (col 4, ln 23-24);

an anchor having a longitudinal axis, a threaded distal end, a proximal end, and an engagement shoulder located therebetween, with the engagement shoulder configured and dimensioned to receive a wrench or similar tool to thread the anchor into the first tissue (col 5, ln 3-40) wherein at least one of the plate and anchor is made of a material that softens and deforms upon the application of ultrasonic energy such that a weld or mechanical interlock between the plate and anchor secures the plate to the first tissue (col 5, ln 15-19; col 6, ln 7-22).

Claims 2-10 lack an inventive step under PCT Article 33(3) as being obvious over Aeschlimann in view of Trieu

As per claim 2, Aeschlimann discloses the weldable plate assembly of claim 1. Aeschlimann does not explicitly disclose wherein said anchor includes a helical thread. Trieu does disclose wherein said anchor includes a helical thread disposed on an outer surface of the distal end that engages with the first tissue or implant material to assist in insertion or removal of the anchor from the first tissue or implant material when the anchor is rotated (col 5, ln 29-40; fig. 7.). Therefore, it would have been obvious to one skilled in the art to have used the threaded screw taught in Trieu in combination with Aeschlimann's taught assembly. Moreover, by using a screw with a helical thread taught by Trieu, provided Aeschlimann's teaching, it would have been obvious to one skilled in the art that using such a screw would have offered the additional strength and functionality intended in the present invention.

As per claim 3, Aeschlimann and Trieu, in combination, disclose the weldable plate assembly of claim 2, and Aeschlimann further discloses wherein the plate further comprises a second receptacle formed on an opposing side of the plate, and wherein said second receptacle is configured to receive a welding instrument for emitting the energy source (para [0057; 0063]).

As per claim 4, Aeschlimann discloses the weldable plate assembly of claim 1. Aeschlimann does not explicitly disclose wherein at least one of the anchor and plate is made of PEEK. Trieu does disclose wherein at least one of the anchor and plate is made of PEEK (col 13, ln 66-67 - col 14, ln 1-6).

As per claim 5, Aeschlimann discloses the weldable plate assembly of claim 1. Aeschlimann does not explicitly disclose wherein the proximal end of the anchor is substantially conical and the distal end of the anchor includes a helical thread disposed on an outer surface. Trieu does disclose wherein the proximal end of the anchor is substantially conical and the distal end of the anchor includes a helical thread disposed on an outer surface (col 5, ln 9-11). It would have been obvious to one skilled in the art to have included such an anchor into Aeschlimann's teaching. Furthermore, one skilled in the art could have interpreted the teaching of Trieu in such a way that a curved or rounded upper profile could be shaped substantially conically, as the geometric configuration of the above referenced shapes could be designed with a substantially conical profile. Therefore, it would have been obvious for one skilled in the art to adapt Trieu's teaching by designing a substantial conically shaped screw, while additionally implementing the use of such a screw in the assembly taught by Aeschlimann, thus providing one skilled in the art with the present invention.

As per claim 6, Aeschlimann and Trieu, in combination, disclose the weldable plate assembly of claim 5, and Aeschlimann further discloses wherein the proximal end of the anchor is substantially smooth (para [0027, 0063, 0072]; fig. 9-11).

As per claim 7, Aeschlimann and Trieu, in combination, disclose the weldable plate assembly of claim 6, and Aeschlimann further discloses wherein the proximal end of the anchor includes a recess for receiving a portion of an end effector (para [0072]).

As per claim 8, Aeschlimann and Trieu, in combination, disclose the weldable plate assembly of claim 7. Aeschlimann does not explicitly disclose wherein the anchor includes an engagement shoulder located between the proximal and distal ends and configured and dimensioned to receive a tool for rotating the anchor. Trieu does disclose wherein the anchor includes an engagement shoulder located between the proximal and distal ends and configured and dimensioned to receive a tool for rotating the anchor (col 5, ln 3-19).

As per claim 9, Aeschlimann and Trieu, in combination, disclose the weldable plate assembly of claim 8. Aeschlimann does not explicitly disclose wherein the width of the engagement shoulder is larger than the largest diameter of the conical proximal end and smaller than the largest diameter of the helical threads of the distal end. Trieu does disclose wherein the width of the engagement shoulder is larger than the largest diameter of the conical proximal end and smaller than the largest diameter of the helical threads of the distal end (col 5, ln 9-29).

As per claim 10, Aeschlimann and Trieu, in combination, disclose the weldable plate assembly of claim 3, and Aeschlimann further discloses an assembly further comprising a plurality of anchors having distal and proximal ends, and wherein the plate comprises a corresponding plurality of first receptacles formed on the first side of the plate for receiving the proximal ends of the anchors and a corresponding plurality of second receptacles on the opposing side of the plate for receiving the welding instrument (para [0057-0058]; fig. 2).

-*-See Supplemental Box-*-

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

Continuation of:
-Supplemental Box-

Claim 12 lacks an inventive step under PCT Article 33(3) as being obvious over Cole in view of Trieu .

As per claim 12, Cole discloses the method of claim 11. Cole does not explicitly disclose wherein at least one of the rod and fastener is formed from PEEK. Trieu does disclose wherein at least one of the rod and fastener is formed from PEEK (col 13, ln 66-67; and col 14, ln 1-6). It would have been obvious to one skilled in the art to perform the method taught by Cole while using Trieu's teaching as motivation to improve upon Cole's disclosure. Moreover, Trieu's teaching of using the material PEEK in such an implant makes it obvious to one skilled in the art that using PEEK to carry out the teachings of Cole would have improved or made compliant Cole's teaching with the desired functionality of the present invention.

Claim 16 lacks an inventive step under PCT Article 33(3) as being obvious over Cole in view of Aeschlimann.

As per claim 16, Cole discloses the method of claim 15. Cole does not explicitly disclose wherein the fastener further comprises a band associating a first post with a second post. Aeschlimann does disclose wherein the fastener further comprises a band associating a first post with a second post (para [0072; 0102]). It would have been obvious to one skilled in the art to have appreciated Aeschlimann's disclosure as motivation to have improved Cole's teaching. Furthermore, Cole's disclosure of welding the fastener to the rod could have been performed as taught by Aeschlimann. Therefore, it would have been obvious to one skilled in the art to have implemented the band (eg. suture, cable, or wire) welding method as taught by Aeschlimann into Cole's teachings, thus resulting in the present invention.

Claims 1-20 have industrial applicability as defined by PCT Article 33(4) because the subject matter can be made or used in industry.